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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,618	04/16/2004	Jian Cao	P-21057.00	1313

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EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	PAPER NUMBER
3762	

MAIL DATE	DELIVERY MODE
06/09/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,618	CAO ET AL.	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/14/2009 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendments to claims 1 and 10 appear to be an unsupported broadening of the claim scope. For instance, Figures 6 and 7 of Applicant's disclosure (and the accompanying textual description) show that an updated template is generated only if the original template is invalid. Thus, an updated template is *not* disclosed as being generated if the original template is found to be valid, contrary to the claim language, which generates an updated template "based on the result" of the

comparison, regardless of validity. It is suggested to recite "generating…if the current template is invalid" or something similar. Additionally, the broadening of the "comparing" clause also appears to be unsupported because the algorithm does not merely obtain *any* result, but obtains a result of whether the current template is valid or invalid.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In regards to claims 1 and 10, it is unclear how an updated template can be generated "based on the result [of the comparing step]" in the case that the comparing step finds the current template to be valid (because no updated template is disclosed as being generated in this case).

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1-9 and 19 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The method claims fail the "machine-or-transformation test" set forth in *In re Bilski* because the method is not tied to a particular machine or apparatus, nor does the method transform an article into a different state or thing. *See In re Bilski,* 545 F.3d 943, 88 USPQ2d 1385 (Fed. Cir. 2008).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 2002/0183637, hereinafter "Kim") in view of Koyrakh et al. (US 2002/0193695, hereinafter "Koyrakh").

11. In regards to claims 1 and 10, Kim discloses a device/method for generating a template of a normal heartbeat comprising detecting a plurality of heartbeats (par. 0007-0010), collecting a first predetermined number of detected non-paced heartbeats having predetermined characteristics (via Figs. 4 and 6), generating a current template from the first selected events, waiting a predetermined delay (par. 0064), collecting a second predetermined number of detected non-paced heartbeats, then determining whether the

template is valid based on a comparison of the collected second selected events with the current template (Fig. 6, "If a Template exists, correlate it with the next 21 template beats" block; and par. 0082-0083), and generating an updated template if the current template is not valid (par. 0010 and Fig. 6) from the collected second beats (Fig. 6; "If not correlated" path). Please note that, although an embodiment utilizes paced and non-paced beats to determine "regularity", these paced beats are not used for template generation, per the rules of paragraph 0078 and 0081. Further, Kim discloses an embodiment without therapy provision per paragraphs 0065 ("monitor mode") and 0041 ("only monitoring of cardiac activity is performed"). As such, all beats are inherently non-paced because no pacing therapy is provided. Although Kim discloses that a collected second selected event is compared to the current template to obtain a result on a beat-by-beat basis (par. 0082), Kim does not disclose that second selected events (plural) are compared with the current template *after* collection of said events. However, Koyrakh teaches a template generation algorithm that utilizes a plurality of second selected events that are compared with a current template after collection of said events (par. 0069) to provide the predictable result of effectively identifying the necessity to replace the current template (par. 0070). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Kim's invention by utilizing a plurality of second selected events that are compared with a current template after collection of said events to provide the predictable result of effectively identifying the necessity to replace the current template.

12. In regards to claims 2 and 11, the template update is repeated (par. 0064).

13. In regards to claims 3 and 12, identifying events as first selected events comprises determining whether consecutive events have a first characteristic (i.e. comprise the first 20 beats) and identifying a predetermined number of subsequent events as second selected events (i.e. comprise the beats subsequent to the 20 beats).

14. In regards to claims 4 and 13, the "monitoring only" embodiment requires that consecutive events have an RR-interval greater than a threshold per paragraph 0071. Further, the "NSR" beats of paragraphs 0078-0081 are consecutive to each other (although they may or may not be consecutive with respect to all heart beats) and have RR-intervals greater than a threshold because they must pass the "regularity" test of 0071.

15. In regards to claims 7, 8, 16 and 17, a cross-match is determined and compared to a threshold and a delay is generated if the threshold comparison fails (par. 0108).

16. In regards to claims 9 and 18, R-R intervals associated with the first events are compared to an average (par. 0071); a cross-match is computed (par. 0105) if the R-R intervals are greater (or less) than the average; and a template is generated from the events corresponding to the cross-matches (par. 0108).

17. In regards to claims 5, 6, 14, 15, and 19, Kim discloses that valid sense events having first and second characteristics comprise the following characteristics: the sense event is not a ventricular pace event (par. 0078), the event has an R-R interval greater than a predetermined rate of about 600 ms (par. 0071), the sense event can comprise events other than those directly following a ventricular pace (par. 0078), and the

ventricular sense event follows an atrial pace event by a predetermined threshold (par. 0081, rule 5) and is about 100 ms (see Fig. 9, ½ of the 320 ms window is the threshold).

Response to Arguments

18. Applicant's arguments with respect to claims 1-19 have been considered but are moot in view of the new ground(s) of rejection, necessitated by amendment. Applicant additionally argued that Kim "teaches away" from a multiple beat comparison because Kim specifically indicates a "beat-to-beat" analysis. However, the Examiner respectfully disagrees that this is a "teaching away" (i.e., that a multiple beat approach should not be used), but only that Kim chose a single beat approach and is silent about a multiple beat approach. Koyrakh is relied upon for this teaching.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762